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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,770	02/19/2002	Karin Golz-Berner	3975.007	6050

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TAMPA, FL 33634-7356

EXAMINER

LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,770

Applicant(s)

GOLZ-BERNER ET AL.

Examiner

HERBERT J. LILLING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-19-02; 6-26-02; 4-30-04.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6-26-02; 4-30-04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

1. Receipt is acknowledged of the two prior art information disclosure statements filed June 26, 2002 and April 30, 2004 plus the preliminary amendment filed February 19, 2002 for this application, which is a 371 of PCT/DE99/03295, filed October 08, 1999.

2. Claims 1-10 and 12-14 are now pending in this application.

Claim 11 has been cancelled.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the following terms:

i. Claim 1, "hydrogel or mixture of hydrogels" which is (are) not defined since the term does not define the component or mixture in physical type of mixture.

ii. Claim 2, the term "extract" in the expression "extract of acerola fruits Malpighia punidifolia" does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims since the term "extract" is a process step for which the claim does not contain the essential process steps for making the extract or

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the extract is not defined which is sufficient to practice the instant invention e.g. in claim 1, part (a) or claim 1 part (b) or claim 1 part (c) or claim 8 parts (1.1 or 1.2) or (2) which Extracts have specific properties or components, which sufficiently describes the component(s).

iii. Claim 2, appears to be in error with respect to the letter (g) which reference is not supported by the instant specification.

iv. Claim 6, there is no antecedent basis for the term "aspartine acid" as well as there is no compound noted in the specification as "aspartinic acid".

v. Claim 9 the term "extract" or "extracts" throughout the claim have been found not to define the product per se or have sufficient properties as noted above does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

vi. Claim 10 is not supported by the instant specification for a composition per se. In addition, the specification does indicate the components in the extract or the process for preparing the extract. It is considered that at least the instant specification is fatally defective to support this claim. It appears that this Examiner will not allow this claim based in the instant specification.

The enablement as well as the written description of the instant specification lack support for the claimed extract(s).

**The specification lacks adequate written description** for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

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The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention."

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The term "extract(s)" does not sufficiently describe a product per se but only a process step.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, that is the "extract", is not a description of that material.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention with respect to the terms:

a. Claim 8 the expression "acerola fruits (*Malpighia punidifolia*) in view of the following:

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance,

Claim 8 recites the broad recitation "acerola fruits, and the claim also recites (Malpighia punidifolia), which is the narrower statement of the range/limitation.

Claim 9 recites the broad recitation "leaf extracts" and the claim also recites (Citrus.....)

Claim 9 contains

The parenthesis should not be employed in the claims.

(b) Claims 1-10 and 12-14 are vague and indefinite by the term "extract", "extracts" or "hydrogel" because the terms, in and of itself, does not adequately delineate its metes and bounds.

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i. An "extract" is necessarily a product-by-process because the composition of the "extract" is only defined by the process of its preparation. Such product-by-process claims are intended to define products, which are otherwise difficult to define and/or distinguish from the prior art except, by the process of making. Since any given plant or other source contains thousands of extractable compounds, each with its own particular extraction properties, the nature of the resulting "extract" will depend on the conditions of the extraction and the solvent used. For example, at what temperature is the extraction performed? Is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, or an acid or base, or is it a squeezed extract? It is well accepted in the natural products and herbal art, that extraction of a plant source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of active ingredients obtained, and, thus, on the ability of the "extract" to provide the desired functional effect(s) claimed and/or disclosed.

ii. A "hydrogel" is a mixture of a colloidal solution of a liquid in a solid with the inclusion of water. This term does not define the components.

Since the "extract", "extracts" or "hydrogel" itself is clearly essential to the instantly claimed invention, the step(s) by which the claimed "extract", "extracts" or "hydrogel" is/are obtained is/are also clearly essential and, therefore, must be recited in the claims (i.e., as a product-by-process). Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by Runge et al, US 6,235,315.

Runge et al clearly anticipates the claimed invention which discloses formulation having lycopene within the claimed range.

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6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

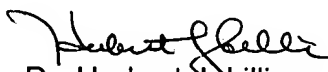
7. **No claim is allowed.**

Examiner will allow all claims commensurate in scope with the claimed inventions fully supported by the instant specification. Applicant is kindly requested to amend claim 1 for part c; correct the antecedent basis for claim 2; delete the term in claim 6; delete "(Malpighia punidifolia)" in claim 8 and add new claim for support of the deleted term; cancel claim 9 unless there is support for one or more of the extract(s) meeting the guidelines set above; delete claim 10 (this claim will not be allowed based on the above paragraph; and 13-14 will be allowed as indicated for claim 1, see specification page 4 for an appropriate amendment.

8. Any inquiry concerning this communication or earlier Communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is (703) 872-9306** or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit **1651**

  
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